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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,555	10/31/2003	Roland Christof Hutter	21686-US	9951

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ROCHE MOLECULAR SYSTEMS INC
PATENT LAW DEPARTMENT
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EXAMINER	
BOWERS, NATHAN ANDREW	
ART UNIT	PAPER NUMBER
1744	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/698,555	HUTTER ET AL.	
	Examiner	Art Unit	
	Nathan A. Bowers	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *1-4* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *060704, 103103*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group II, claims 5-25 in the reply filed on 01 February 2007 is acknowledged.

Claims 1-4 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 01 February 2007.

Claim Objections

Claim 13 is objected to because of the following informalities: the phrase "located substantially in face of" is grammatically awkward. Appropriate correction is required.

Claim 25 is objected to because of the following informalities: the claim is dependent on claim 1, which is a withdrawn method claim. It is understood that the claim should be dependent on claim 9. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1) Claims 9-12, 21 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Lehmann (US 1161984).

With respect to claims 9 and 24, Lehmann discloses a reaction vessel for processing a biological sample contained in a liquid. The vessel includes a tubular body (Figure 1:15) having a bottom wall, an upper opening (Figure 1:13), and sidewalls which extend between the bottom wall and the upper opening. The bottom wall and the sidewalls form a chamber (Figure 5:33) for receiving a liquid to be processed. A chip shaped carrier (Figure 2:21) having an active surface (Figure 2:32) is accessible to liquid contained in the chamber. The chip shaped carrier is located in an opening (Figure 2:18) in the sidewall of the tubular body. This is disclosed in paragraphs [0021]-[0025], [0032] and [0033].

With respect to claim 10, Lehmann discloses the reaction vessel in claim 9 wherein the tubular body is *configured and dimensioned* such that an air space exists between the free surface of the liquid and the upper opening. The tubular body is also *adapted* such that the entire active surface is in contact with the liquid contained in the chamber. Although Lehmann does not clearly describe these limitations, the disclosed device is *configured and dimensioned* in such a way that it is capable of fulfilling these requirements.

With respect to claim 11, Lehmann discloses the reaction vessel in claim 9 wherein the chip shaped carrier is located at a predetermined distance fro the bottom wall and from the upper opening of the tubular body. This is apparent from the Figures.

With respect to claim 12, Lehmann discloses the reaction vessel in claim 9 wherein the chip shaped carrier is transparent to enable performing electro-optical measurements of the active surface. In paragraph [0024], Lehmann indicates that the carrier is made of glass.

With respect to claim 21, Lehmann discloses the reaction vessel in claim 9 wherein the active surface of the carrier has the shape of a square having side lengths between 2 to 10 millimeters. This is disclosed in paragraph [0034].

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2) Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lehmann (EP 1161984) in view of Vischer (EP 1224976).

Lehmann discloses the reaction vessel as previously described above. Lehmann, however, does not expressly indicate that the vessel is in communication with a vessel holder capable of moving along a predetermined trajectory.

Vischer discloses a system from processing a biological sample in which a reaction vessel (Figure 6:12) comprising a chip shaped carrier (Figure 2:14) is coupled to a vessel holder (Figure 6:16). Figures 6 and 7 and paragraphs [0035] and [0036] state that the vessel holder is moved along a predetermined trajectory for causing a relative motion of liquid contained in the reaction vessel with respect to the active surface of the chip shaped carrier.

Lehmann and Vischer are analogous art because they are from the same field of endeavor regarding reaction vessels.

At the time of the invention, it would have been obvious to utilize a moving means such as described by Vischer to influence mixing within the reaction vessel disclosed by Lehmann. Vischer indicates in paragraphs [0009]-[0011] that mixing

means are beneficial because they allow one to provide effective contact between the sample solution and the active surface of the chip shaped carrier. The specific mixing mechanism of Vischer is advantageous because it is highly reproducible, inexpensive, and more reliable than other mixing devices that are based on liquid circulation via pumping.

3) Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable Lehmann (EP 1161984) in view of Vischer (EP 1224976) as applied to claim 5, and further in view of Frackleton (US 5133937).

Lehmann and Vischer disclose the apparatus set forth in claim 5 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly indicate that a heat transfer element is provided for heating and cooling the contents of the reaction vessel.

Frackleton discloses a system for processing a biological sample contained in a liquid. Frackleton teaches that a reaction vessel (Figure 1:90) is coupled to a vessel holder (Figure 1:30) that comprises various heat transfer elements (Figure 1:62 and Figure 1:124). This is described in column 3, line 12 to column 4, line 48.

Lehmann, Vischer and Frackleton are analogous art because they are from the same field of endeavor regarding biological sample processing devices.

At the time of the invention, it would have been obvious to incorporate heat transfer elements in the system disclosed by Lehmann and Vischer. In column 1, lines 14-18, Frackleton indicates that biological analytical reactions are frequently temperature sensitive, and therefore require accurate temperature control. The heating

and cooling mechanisms described by Frackleton are considered to be well known in the art.

4) Claims 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable Lehmann (EP 1161984) in view of Vischer (EP 1224976) as applied to claim 5, and further in view of Frackleton (US 5133937).

With respect to claim 13, Lehmann discloses the apparatus set forth in claim 9 as set forth in the 35 U.S.C. 102 rejection above, however does not expressly indicate that the sidewall across from the chip shaped carrier is transparent.

Frackleton discloses a system for processing a biological sample contained in a liquid. Frackleton teaches that a reaction vessel (Figure 1:90) is coupled to a vessel holder (Figure 1:30) that includes a transparent face plate (Figure 9:52) that permits visual observation of the sample.

Lehmann and Frackleton are analogous art because they are from the same field of endeavor regarding biological sample processing devices.

At the time of the invention, it would have been obvious to ensure that the sidewalls of the apparatus disclosed by Lehmann were transparent to promote visual observation of the reaction area. The use of optical detection systems that incorporate a clear, transparent window is considered to be well known in the art. In paragraph [0022], Lehmann suggests that the optically non-transparent sidewalls might be constructed so that they are transparent in other embodiments.

With respect to claims 14-16, Lehmann discloses the apparatus set forth in claim 9 as set forth in the 35 U.S.C. 102 rejection above, however does not expressly indicate that a heat transfer element is provided for heating and cooling the contents of the reaction vessel.

Frackleton discloses a system for processing a biological sample contained in a liquid. Frackleton teaches that a reaction vessel (Figure 1:90) is coupled to a vessel holder (Figure 1:30) that comprises various heat transfer elements (Figure 1:62 and Figure 1:124). This is described in column 3, line 12 to column 4, line 48.

At the time of the invention, it would have been obvious to ensure that the device disclosed by Lehmann was capable of interacting with various heat transfer elements. In column 1, lines 14-18, Frackleton indicates that biological analytical reactions are frequently temperature sensitive, and therefore require accurate temperature control. The heating and cooling mechanisms described by Frackleton are considered to be well known in the art.

5) Claims 17-20, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lehmann (EP 1161984) as applied to claim 9.

With respect to claims 17-20, Lehmann discloses the apparatus set forth in claim 9 as set forth in the 35 U.S.C. 102 rejection above, however does not provide specific dimensions describing the volume of the reaction chamber. Regardless, it would have been obvious to ensure that the chamber was a cubiod having side lengths of at least 3 millimeters if it was determined that this volume produced the most effective results.

Reaction chamber side lengths are considered result effective variables that are optimized through routine experimentation. At the time of the invention, it would have been apparent to fashion the reaction chamber disclosed by Lehmann according to the specifications presented in claims 17-20 if it was determined that these measurements allowed the device to function at an optimum level.

With respect to claims 22 and 23, Lehmann discloses the apparatus set forth in claim 9 as set forth in the 35 U.S.C. 102 rejection above, however does not expressly indicate that the reaction vessel includes a removable cap. However, removable caps are considered to be notoriously well known in the art. Essentially any removable cap would be capable of interacting with the gripper of a transport mechanism.

6) Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lehmann (EP 1161984) as applied to claim 9, and further in view of Mochida (GB 2129551).

Lehmann discloses the apparatus set forth in claim 9 as set forth in the 35 U.S.C. 102 rejection above, however does not expressly indicate that the sidewalls carry a barcode label.

Mochida discloses the use of immunoassay vessels (Figure 1:1) that utilize barcode labels (Figure 1:2) as a tracking mechanism. This is disclosed on page 3, lines 60-64.

Lehmann and Mochida are analogous art because they are from the same field of endeavor regarding biological analysis devices.

At the time of the invention, it would have been obvious to include a bar code label on the outer sidewalls of the reaction vessel disclosed by Lehmann. Bar codes are helpful in quickly sorting and tracking reaction vessels, and they can be used to immediately determine the identity of a specified reaction vessel in the presence of a plurality of otherwise identical reaction vessels, thus reducing confusion and the occurrence of mistakes.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Schulz (US 20050064469), Anderson (US 7179638) and Kraffczyk (US 3884641) reference disclose the state of the art regarding reaction vessels containing chip shaped carriers and/or biological polymer arrays.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NAB

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SUPERVISORY PATENT EXAMINER